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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,477	11/13/2000	Isabelle Preuilh	2365-23	4547

7590

04/08/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/709,477

Applicant(s)

PREUILH ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-33 and 35-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-33 and 35-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 31-33, 35-61 are pending. The Amendment filed 11/14/02, Paper No. 13, amended claims 33, 50 and 51.

Applicant's arguments with respect to claims 31-33, 35-61 have been considered but are moot in view of the new ground(s) of rejection.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 50 and 51 are vague and indefinite, as they are confusing. What ratio is being claimed? What is "the weight ratio active material of anionic surfactant/active material of amphoteric surface" in claim 50? What is "the weight ratio active material of anionic surfactant/propenetrating agent"? Regarding claim 50, are the ratios with the active materials, or between surfactants? Regarding claim 51, are the ratios with the active materials or of the

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anionic surfactant to the propenetrating agent? Furthermore, what are the active materials? Are active materials the same as active principles, as recited in claim 31?

(ii) The phrase "a derivative of an aliphatic secondary or tertiary amine in which the aliphatic radical is a linear or branched chain comprising 8 to 22 carbon atoms and comprising at least one water-solubilizing anionic group" in claim 40 (lines 2-4) is vague and indefinite, as it is confusing. What is encompassed by the term derivative? This term is not defined in the specification and one of ordinary skill in the art would not be apprised of its meaning. Furthermore, the phrase "water-solubilizing anionic group" is confusing, as it is not clear what compounds this phrase is referring to. The specification does not define this phrases and one of ordinary skill in the art would not be apprised of its meaning.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 37-51, 55, 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Preuilh et al. (6,106,848) and in view of The Handbook of Cosmetic Science and Technology.

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative, and other ingredients, wherein the detergent can be a combination of sodium lauryl sulfate and coamidopropyl betaine. The

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reference fails to teach propenetrating agents, the combination of anionic and amphoteric surfactant, and fails to explicitly state the pH. See Col. 1, line 5-Col. 6, line 35.

Preuilh et al. teach topically applicable compositions for the treatment of skin differentiation and/or proliferation and/or pigmentation, inflammation, microbial infection. Propylene glycol is taught as a pro-penetrating agent for corticoids. The pH of the cosmetic composition is 5-7. See Col. 6, lines 40-Col. 7, line 9.

The Handbook of Cosmetic Science and Technology teaches that amphoteric surfactants provide foam stabilization in combination with the ability to mitigate irritancy of other materials, such as primary surfactants, and, in some cases, will modify product viscosity. They are taught as compatible with anionic surfactants, wherein anionic surfactants are taught as primary surfactants. See pages 220-224.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add propylene glycol, as taught by Preuilh et al., to the composition of Cameron because of the expectation of achieving a composition in which the corticoid is facilitated in penetrating the skin and is, thus, more potent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Cameron comprising both the anionic and amphoteric surfactants because of the expectation of achieving a composition that is more stable and decreases irritation.

While the percent weight of the propenetrating agent and the ratio of anionic to amphoteric surfactant is not taught, it is respectfully pointed out that it has been held that where

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the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 33, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Preuilh et al. and in view of the Handbook of Cosmetic Science and Technology as applied to claims 31, 32, 37-51, 55, 57-61 above, and further in view of Kligman (5,998,395).

Cameron, Preuilh et al, and the Handbook of Cosmetic Science and Technology are applied as discussed above. The reference does not teach preferred corticoids and retinoids.

Kligman teach methods of treating inflammatory dermatosis. Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition and the retinoid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments, or liquids. Further examples of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. The retinoids can be natural or synthetic. See Col. 1, line 19-Col. 12, line 20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the corticoids and retinoids taught by Kligman into the composition of the combined references because of the expectation of achieving a composition that exhibits a synergistic effect in treating chronic dermatoses, such as seborrheic dermatitis, atopic dermatitis, contact dermatitis, psoriasis, and others, and because it is obvious to combine individual

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compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980).

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron in view of Preuilh et al. and in view of the Handbook of Cosmetic Science and Technology as applied to claims 31, 32, 37-51, 55, 57-61 above, and further in view of Cauwet et al. (5,661,118).

Cameron, Preuilh et al., and the Handbook of Cosmetic Science and Technology are applied as discussed above. The reference does not teach cationic polymers and ceramides.

Cauwet et al. teach hair and skin washing and treatment compositions based on ceramide and/or glycoceramide and cationic polymers. The combination of cationic polymer and ceramic and/or glycoceramide provides synergistic disentangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guar hydroxypropyltrimonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition. See Col. 13, line 1-Col. 20, line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the cationic polymer and ceramide taught by Cauwet et al. to the composition of the combined references because of the expectation of achieving a shampoo composition with synergistic disentangling effects.

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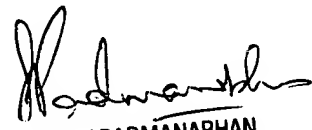
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
March 12, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 4/4/03